REMARKS

Status of the Claims

Claims 1-2, 4-8, 10-50 and 52-79 are currently pending in the application.

Claims 5, 7, 12 and 57 are amended with entry of this amendment.

Claims 32-40, 52-53 and 65-67 were withdrawn by the Office.

Claims 54-56 were improperly withdrawn by the Office and have been re-added with entry of this amendment.

Claims 1-2, 4-8, 10-31, 41-50 and 54-64 and 68-79 remain under consideration with entry of this amendment.

Summary

Claims 1-2, 4-8, 10-50 and 52-79 are pending in the application and were examined in the Office Action dated 11 September 2007. In the subject Office Action, the Office withdrew claims 32-40, 52-56 and 65-67 as drawn to non-elected species. In addition, the following claim rejections have been raised: **(a)** claims 1, 2, 4, 6, 10, 11, 13-31, 41-50, 57-63 and 68-79 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite; (**b**) claims 1, 2, 4-6, 10-13, 17, 18, 23-30, 46-50, 57, 70, 71 and 76-78 stand rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,747,058 to Tipton et al. ("Tipton"); (**c**) claims 7, 8, 14-16, 19-22, 41-45, 58-62, 68-71, 73-76 and 79 stand rejected under 35 U.S.C. §103(a) as unpatentable over Tipton; and **(d)** claims 31, 63, 64 and 72 stand rejected under 35 U.S.C. §103(a) as unpatentable over Tipton. Applicants respectfully traverse all pending claim rejections for the following reasons.

Overview of the Amendments

Applicants, by way of this Response, have amended claims 5, 7, 12 and 57 in order to recite the invention with greater particularity. More specifically, these claims have been amended to provide initial designation for the following abbreviations recited in the claims: SAIB; CAB; IPM; EL; DMSO; NMP and PEG. Support for these

amendments can be found in the specification as originally filed. Accordingly, no new matter has been added by way of the claim amendments, and the entry thereof is respectfully requested.

In addition, applicants have re-added claims 54-56 that were improperly withdrawn by the Office. In particular, applicants elected Species (b) -- Ethyl Lactate as the elected solvent -- in their last Response (dated 12 June 2007). Ethyl Lactate is the ester of lactic acid (an organic acid) and contains an alcohol group. Therefore, the Ethyl Lactate molecule is an organic acid derivative (claim 54), it is also an organic acid ester (claim 55) and it comprises an alcohol and an organic acid residue (claim 56). See paragraph [0040] of the published specification. For this reason, the elected Species (b) reads on claims 54-56 which are generic to that species. Re-entry and examination of claims 54-56 is thus respectfully requested.

The Rejections under 35 U.S.C. §112, Second Paragraph

Claims 1, 2, 4, 6, 10, 11, 13-31, 41-50, 57-63 and 68-79 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite. In particular, the Office has objected that: (a) the boundaries of the claim limitation "high viscosity liquid carrier material (HVLCM)" are "not clear"; (b) the boundaries of the claim limitation "network former" are "not clear"; and (c) the boundaries of the claim limitation "rheology modifier" are "not clear". See Office Action at pages 2-3, bridging paragraph. Applicants respectfully traverse the rejection

In assessing a claim for compliance with 35 U.S.C. §112, second paragraph, one must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope, therefore providing the notice function of 35 U.S.C. §112, second paragraph. See *Solomon v. Kimberly-Clark Corp.*, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). In providing this notice function, a patent applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claims that make clear the boundaries of the subject matter for which protection is sought. In fact, a claim may not be rejected solely on the basis of the type of language

used to define the subject matter for which patent protection is sought. *In re Swinehart*, 160 USPQ 226 (CCPA 1971).

Turning to the Office's first objection, regarding high viscosity liquid carrier materials (HVLCMs), this is a term of art that has been widely used in granted US patent claims and scientific publications since 1995. See, e.g., US Patent Nos 5,747,058; 5,968,542; and 6,413,536. As expressly defined in applicants' specification, a HVLCM is a member of a discrete, limited group of special liquid carrier materials that have 5 important chemical/physical properties. These are: **(1)** the materials must be non-polymeric; **(2)** the materials must be water insoluble; **(3)** the materials must be a liquid; **(4)** the materials must have a very high viscosity at normal human body temperatures (at least 5,000 cP at 37° C); and **(5)** the materials must not solidify (do not crystallize) by themselves at normal room temperature and pressure (under ambient conditions) nor upon contact with, or insertion into living tissue (under physiological conditions). See Paragraph [0037] of the published specification. Whether or not a candidate liquid carrier material possesses all of these physical/chemical properties can be readily ascertained by the skilled person, using standard testing approaches readily available to the skilled person. Accordingly, use of the term "HVLCM" in the claims is not indefinite since it clearly informs one of ordinary skill in the art of the scope of the claims, therefore providing the notice function of 35 U.S.C. §112, second paragraph.

Turning now to the Office's second objection (regarding use of the term "network former"), applicants draw the Office's attention to Paragraphs [0039] [0052] [0075] and [0076] of the published specification. As can be seen, applicants have provided clear and definite guidance regarding the critical function of this component in their claimed compositions. Applicants have further provided numerous examples of suitable network formers, further clarifying the boundaries of the subject matter for which protection is sought. Whether or not a candidate network former material possesses such expressly defined physical/chemical functions in a pharmaceutical composition can be readily ascertained by the skilled person, using standard testing approaches readily available to the skilled person. Accordingly, use of the term "network former" in the claims is not

indefinite since it clearly informs one of ordinary skill in the art of the scope of the claims, therefore providing the notice function of 35 U.S.C. §112, second paragraph.

Finally, turning to the Office's third objection (regarding use of the term "rheology modifier"), applicants draw the Office's attention to Paragraphs [0038] [0053] [0070] and [0079] of the published specification. As can be seen, applicants have provided clear and definite guidance regarding both the critical chemical properties (necessity for hydrophobic/hydrophilic moieties and certain partition coefficient requirements) as well as the functional properties (modification, that is, lowering of viscosity and flow properties of a liquid) of this critical component in their claimed compositions. Applicants have further provided numerous examples of suitable rheology modifiers, further clarifying the boundaries of the subject matter for which protection is sought. Whether or not a candidate rheology modifier material possesses such expressly defined physical/chemical function in a pharmaceutical composition can be readily ascertained by the skilled person, using standard testing approaches readily available to the skilled person. Accordingly, use of the term "rheology modifier" in the claims is not indefinite since it clearly informs one of ordinary skill in the art of the scope of the claims, therefore providing the notice function of 35 U.S.C. §112, second paragraph.

For all of the foregoing reasons, then, applicants submit that the use of the claim terms "HVLCM" "network former" and "rheology modifier" are sufficiently clear and definite to meet the requirements of 35 U.S.C. §112, second paragraph. Reconsideration and withdrawal of the rejection of claims 1, 2, 4, 6, 10, 11, 13-31, 41-50, 57-63 and 68-79 under 35 U.S.C. §112, second paragraph, is thus earnestly solicited.

The Rejection under 35 U.S.C. §102(b)

Claims 1, 2, 4-6, 10-13, 17, 18, 23-30, 46-50, 57, 70, 71, and 76-78 stand rejected under 35 U.S.C. §102(b) as anticipated by Tipton. In particular, the Office asserts "Tipton discloses a composition comprising a HVLCM (with sucrose acetate isobutyrate specifically employed ... the composition contains surfactants ... oily components ... ethyl lactate ... preservatives, antioxidants, stabilizers, vitamins ... drugs such as codeine [and] the formulation of Tipton is placed in gelatin capsules for oral administration." The

Office then concludes "the composition of Tipton would inherently possess the characteristics of [applicants' recited composition]." Office Action at page 4. Applicants respectfully traverse the rejection.

Tipton cannot anticipate applicants' claims since a claim is anticipated only if each and every element as set forth in the claim is described in a single prior art reference, that is, the identical invention must be shown in the prior art reference in as complete detail as is contained in the claim. See, e.g., *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051 (Fed. Cir. 1987); and *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913 (Fed. Cir. 1989). The basis on which anticipation is measured is whether or not the prior disclosure is an "enabled disclosure" and this is particularly important when a theory of inherency is being used, as is the case in the instant rejection. *In re Samour*, 197 USPQ 1 (CCPA 1978).

In the instant rejection, the Office has characterized Tipton as disclosing "a" composition that meets all of applicants' recited limitations. This is clearly incorrect. Tipton does not disclose a single, particular composition as recited in applicants' claims (an oral pharmaceutical composition that includes a HVLCM, a solvent, a rheology modifier and a network former). Tipton instead generally discloses pharmaceutical compositions that include a HVLCM component. However, these compositions may be provided in the form of topical, systemic, mucosal, oral, rectal, vaginal, nasal, or parenteral (intravenous, subcutaneous, intramuscular, intraperitoneal) pharmaceutical compositions. The Tipton compositions may be poured, sprayed dipped, aerosolized or coated, injected as a solution in the form of liquid, applied as a paste or emulsion, provided as an oral topical delivery system, provided in the form of a mouthwash and the like. See Tipton, column 10, line 39 through column 11, line 30. The various Tipton compositions can include one or more of a large list of active ingredients (see Tipton, column 6, line 50 through column 8, line 18. Optionally, the compositions can include any number of a large list of biodegradable polymers (see Tipton, column 9, lines 6-27), non-biodegradable polymers (see Tipton, column 9, lines 28-41). Further optional components can include any number materials found in a vast list of oils and fats (see Tipton, column 9, lines 42-60), any number materials found in an extensive list of

carbohydrates and carbohydrate derivatives (see Tipton, column 9, line 61), and any number of materials found in an extensive list of surfactants and co-surfactants (see Tipton, column 11, line 40 through column 12, line 12). Still further, the Tipton composition can include any number of solvents selected from yet another vast list of suitable materials (see Tipton, column 10, lines 1-30). Still even further, the Tipton compositions may contain further optional materials such as preservatives, stabilizers, antioxidants, coloring agents, isotonic agents, flavorings, humectants, sequesterants, vitamins and vitamin precursors (see Tipton, column 12, lines 65-67).

In sum, there is not simply just one composition disclosed by Tipton as the Office has asserted, wherein that composition "inherently" possess all of the characteristics of applicants' recited compositions. In fact, there are literally millions of different combinations of the above-described "optional" ingredients with Tipton's HVLCM, and these in turn can be provided in numerous different pharmaceutical dosage forms. Tipton fails to disclose applicants' recited composition, which is a novel combination of elements (an oral pharmaceutical composition that includes a HVLCM, a solvent, a rheology modifier and a network former), and thus fails to disclose the identical invention, that is, applicants' recited combination, in as complete detail as is contained in applicants' claim. Tipton cannot anticipate applicants' claims without this requisite disclosure – neither expressly nor inherently. For all of these reasons, then, applicants respectfully submit that the rejection of claims 1, 2, 4-6, 10-13, 17, 18, 23-30, 46-50, 57, 70, 71, and 76-78 under 35 U.S.C. §102(b) as anticipated by Tipton is improper and simply not supported by the record. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

The Rejections under 35 U.S.C. §103(a)

Claims 7, 8, 14-16, 19-22, 41-45, 58-62, 68-71, 73-76 and 79 stand rejected under 35 U.S.C. §103(a) as obvious over Tipton. In particular, the Office asserts that Tipton "describes compositions that contain CAB and HVLCM and solvents separately." Even though the Office acknowledges that Tipton "does not disclose one composition that has HVLCM, CAB, solvent and rheology modifier" the Office nonetheless concludes "since

Tipton teaches these compositions separately, it would have been obvious to combine two compositions to form a third composition that would be used for the same purpose." See Office Action at page 5. Applicants respectfully traverse the rejection for the following reasons.

The Patent Office bears the burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103(a). *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). According to the Federal Circuit, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007). Furthermore, the Supreme Court has stated that "it will [often] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).

Turning to the rejected claims, applicants have disclosed and claimed a specific composition (an oral pharmaceutical composition that includes a HVLCM, a solvent, a rheology modifier and CAB as a network former). These compositions represent a substantial contribution to the art, particularly, the compositions provide optimal, sustained delivery of the drug of interest from the composition under normal (oral) administration, yet resist delivery of the same drug from the composition under mechanical (crushing or powdering) or solvent extraction (alcohol or water) conditions that could be used to abuse the drug. See Paragraph [0062] and the working examples of the published specification. These requirements: (1) where the composition must freely release the drug in the solvent extraction environment of the stomach; and (2) not release the drug in other solvent extraction environments (water, alcohol), are complete opposites of one another. If one wishes to increase the "abuse resistance" properties of the dosage form and make the drug less extractable from the composition, one would expect that the

subject composition would then become less efficient for delivery (extraction) under normal administration conditions. On the other hand, if one wishes to increase the drug delivery efficiency of the dosage form, one would expect that the composition would then become less abuse-resistant, that is, more susceptible to drug extraction. It is therefore surprising and non-obvious that applicants' recited compositions provide both optimal drug delivery under intended administration conditions and superior abuse-resistant properties under conditions of drug abuse.

Contrary to the Office's assertions, it was not obvious to combine specific elements from seven individual lists of materials disclosed by Tipton (the dosage form list, the HVLCM list, the solvent list, the optional element list (including surfactants and oily components), and the polymer lists (biodegradable and non-biodegradable) to wind up with an oral dosage form that has the HVLCM component, a solvent component, a rheology modifier component, and CAB as a network former component. The Office has already taken the position that just the selection of a particular solvent from a list such as that provided by Tipton or applicants' disclosure represents a patentably distinct species of invention capable of supporting different patents in the art (see the Species Election Requirement in the Office Action dated 12 February 2007, page 2). It would thus seem to follow that each and every other selection (a particular dosage form, a specific polymer additive, a specific additional additive (surfactant/oily component) from the different lists found in the Tipton reference would also represent distinct and non-obvious choices. Furthermore, selecting specific elements from multiple such lists and then assembling them into a specific combination as required by applicants' claims represents yet another non-obvious step away from the Tipton disclosure. In this regard, the Office has failed to identify a single apparent reason to combine the known elements from Tipton into the specific combination recited by applicants' claims. In addition, the Office has failed to identify a single apparent reason that applicants' specific combination would have such surprising properties that provide both optimal drug delivery under intended extraction conditions and optimal abuse resistant properties under non-intended extraction conditions.

In short, the Office has failed to establish a *prima facie* case of obviousness over Tipton since the Office fails to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the specific composition recited in applicants' claims, having applicants' unique performance characteristics, and would have had a reasonable expectation of success in doing so. Accordingly, applicants respectfully submit that the rejection of claims 7, 8, 14-16, 19-22, 41-45, 58-62, 68-71, 73-76 and 79 under 35 U.S.C. §103(a) as obvious over Tipton is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

Claims 31, 63, 64 and 72 stand rejected under 35 U.S.C. §103(a) as obvious over Tipton. In particular, the Office asserts "one of the drugs in Tipton is codeine, which is an opioid ... Tipton does not teach oxycodone ... [but] since oxycodone and codeine are opioids ... it is *prima facie* obvious that oxycodone can be used in place of codeine." Office Action at page 6. Applicants respectfully traverse the rejection.

More particularly, applicants draw the Office's attention to the traversal provided herein above where applicants established that it was not obvious to combine specific elements from seven individual lists of materials disclosed by Tipton (the dosage form list, the HVLCM list, the solvent list, the optional element list (including surfactants and oily components), and the polymer lists (biodegradable and non-biodegradable) to wind up with an oral dosage form that has the HVLCM component, a solvent component, a rheology modifier component, and CAB as a network former component. Here, the Office has added an 8th list to choose from – namely the list of biologically active agents and drugs. Since it was non-obvious when one had 7 lists to select from, it certainly remains non-obvious with the addition of yet another list from which to choose a specific element to add to the combination.

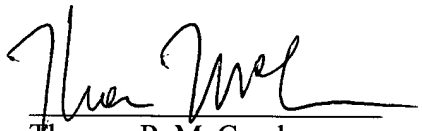
Accordingly, the Office has failed to establish a *prima facie* case of obviousness over Tipton since the Office fails to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the specific composition recited in applicants' claims, having applicants' unique performance characteristics, and would have had a reasonable expectation of success in doing so. Accordingly, applicants respectfully submit that the rejection of claims 31, 63, 64 and 72

under 35 U.S.C. §103(a) as obvious over Tipton is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

CONCLUSION

Applicants submit that the pending claims define an invention that is both novel and nonobvious over the cited art, and thus all claims are in condition for allowance. Acknowledgement of this by the Office in the form of an early allowance is thus respectfully requested. In addition, if the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, applicants invite the Examiner to contact the undersigned at (408) 777-4915.

Respectfully submitted,



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